



## Summary of Studies Supporting USDA Product Licensure

Establishment Name	Boehringer Ingelheim Animal Health USA Inc.
USDA Vet Biologics Establishment Number	124
Product Code	1901.R4
True Name	Rabies Vaccine, Live Canarypox Vector
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	
Date of Compilation Summary	May 17, 2019

**Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.**

<b>Study Type</b>	Efficacy
<b>Pertaining to</b>	Rabies
<b>Study Purpose</b>	To evaluate efficacy against rabies thirty-six months post-vaccination to establish a 3 year revaccination interval.
<b>Product Administration</b>	One dose subcutaneously
<b>Study Animals</b>	A total of 63 cats, 61 to 69 days of age at time of vaccination  Vaccinates: 32 Controls: 31
<b>Challenge Description</b>	Challenged 1106 days after vaccination with virulent rabies virus
<b>Interval observed after challenge</b>	Cats were observed for 90 days post-challenge
<b>Results</b>	Efficacy was based on clinical signs of rabies (mortality) as confirmed by positive fluorescent antibody (FA) testing for rabies per 9 CFR 113.209  Raw data shown on attached pages.
<b>USDA Approval Date</b>	May 6, 2013

## CONTROLS

### Mortality and Presence of Rabies Antigen in Brain Tissue

ID	Mortality Days PC*	Rabies Antigen (FA)
GDR1	10	+
GDR4	10	+
GDS1	19	+
GDS2	-	-
GDU1	10	+
GDU2	16	+
GDU3	-	-
NID4	12	+
NIF1	12	+
NIF2	13	+
NIG2	15	+
NII2	17	+
NIJ1	16	+
NIJ3	-	-
NIK1	10	+
NIK4	11	+
NIK5	11	+
NIK7	12	+
NIL3	15	+
NIM1	17	+
NIM3	12	+
NIN2	12	+
NIN3	10	+
NIN5	11	+
VEJ3	26	+
VEK1	9	+
VEK3	10	+
VEK5	10	+
VEL2	-	-
VEM4	8	+
VEM5	11	+

\*Animals that did not succumb to rabies infection were euthanized 91 days post-challenge (PC).

+ is positive for rabies virus infection.

- is negative for rabies virus infection.

## VACCINATES

### Mortality and Presence of Rabies Antigen in Brain Tissue

ID	Mortality Days PC*	Rabies Antigen (FA)
GDR2	-	-
GDR3	-	-
GDS3	-	-
GDU4	-	-
GDU5	-	-
GDU6	-	-
GDV6	9	+
GDW4	-	-
GDX1	-	-
NIF3	-	-
NIF6	-	-
NIG1	-	-
NIG3	-	-
NII1	-	-
NIJ2	-	-
NIK2	-	-
NIK3	-	+
NIK6	-	-
NIL2	13	+
NIM2	-	-
NIM4	-	-
NIM5	-	-
NIN1	-	-
NIN4	-	-
VEI2	-	-
VEJ1	-	-
VEJ2	-	-
VEK2	-	-
VEK6	-	-
VEL1	-	-
VEM2	-	-
VEM3	-	-

\*Animals that did not succumb to rabies infection were euthanized 91 days post-challenge (PC).

+ is positive for rabies virus infection.

- is negative for rabies virus infection.

<b>Study Type</b>	Safety
<b>Pertaining to</b>	ALL
<b>Study Purpose</b>	To evaluate safety under field conditions
<b>Product Administration</b>	Subcutaneously (SQ)
<b>Study Animals</b>	Cats
<b>Challenge Description</b>	
<b>Interval observed after challenge</b>	
<b>Results</b>	Study data were evaluated by USDA-APHIS prior to product licensure and met regulatory standards for acceptance at the time of submission. No data are published because this study was submitted to USDA-APHIS prior to January 1, 2007, and APHIS only requires publication of data submitted after that date.
<b>USDA Approval Date</b>	December 4, 1998